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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,882	06/14/2005	Syunichirou Oshima	273243US0PCT	8838
22850	7590	03/07/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			TONGUE, LAKIA J	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/538,882	OSHIMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/1/05</u> .  | 6) <input type="checkbox"/> Other: ____                                     |

### **DETAILED ACTION**

Claims 1-3 are pending and under consideration.

#### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on September 1, 2005 is in compliance with the provisions of 37 CFR 1.97 and has been considered by the examiner.

#### ***Specification***

3. The disclosure is objected to because of the following informalities: Throughout the instant specification, particularly on page 1, the pathogens of the cold-water disease are misspelled. "*Flavobacterium psychrophilium*" should be spelled *Flavobacterium psychrophilum*. "*Flexibactor cyclophils*" should be spelled *Flexibacter psychrophilus*. "*Cytophagar cyclophils*" should be spelled *Cytophaga psychrophila*.

Appropriate correction is required.

4. The use of multiple trademarks has been noted in this application, particularly on page 6. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Claim Objections***

5. Claims 1-3 are objected to because of the following informalities:

*"Flavobacterium psychrophilium"* is misspelled and should be spelled *Flavobacterium psychrophilum*. Appropriate correction is required.

6. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner is unclear what applicant intends by "as an effective component", "an effective dosage" and "components of the cells". Clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Please note that in view of the priority statement which was set forth above the following art rejections are made based upon the filing date of December 17, 2003.

8. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Masunari et al (Efficacy of vaccination for coldwater disease in Ayu *Plecoglossus altivelis*, Bulletin of the Fisheries Experiment Station, Okayama Prefecture, 2001; 16: 49-57 (translation pages 1-14)).

Claims 1-2 are drawn to a vaccine against the cold-water disease in fish, comprising, as an effective component, inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

Masunari et al discloses a vaccine comprising formalin-killed *Flavobacterium psychrophilum* cells. Moreover, Masunari et al discloses that the vaccine is to be used for cold-water disease in Ayu (fish) (page 4, paragraph 3; title). The vaccine of the prior art is the same of that which is claimed.

9. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Masunari et al (Efficacy of vaccination for coldwater disease in Ayu *Plecoglossus altivelis*, Bulletin of the Fisheries Experiment Station, Okayama Prefecture, 2001; 16: 49-57 (translation pages 1-14)).

Claim 3 is drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

Masunari et al discloses a method for preventing the cold-water disease in fish, comprising administering 0.05 ml of inactivated cells of *Flavobacterium psychrophilum* to fish (page 4, paragraph 4). The method of the prior art is the same of that which is claimed.

10. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Rahman et al (The outer membrane fractions of *Flavobacterium psychrophilum* induces protective immunity in rainbow trout and ayu, Fish and Shellfish Immunology, 2002; 12: 169-79).

Claims 1-2 are drawn to a vaccine against the cold-water disease in fish, comprising, as an effective component, inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

Rahman et al discloses a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction (abstract). Rahman et al discloses that the bacterin was inactivated with formalin (page 170, preparation of the vaccines). The vaccine of the prior art is the same of that which is claimed.

11. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Rahman et al (The outer membrane fractions of *Flavobacterium psychrophilum* induces protective immunity in rainbow trout and ayu, Fish and Shellfish Immunology, 2002; 12: 169-79).

Claim 3 is drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

Rahman et al discloses a method for preventing cold-water disease in rainbow trout and ayu (abstract). Moreover, Rahman et al discloses that the fish were immunized with a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction (abstract, page 171-vaccination). The method of the prior art is the same of that which is claimed.

12 Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al (Changes in the cell structure of *Flavobacterium psychrophilum* with length of culture, Microbiol. Immunol., 2001; 45(12): 813-18).

Claims 1-2 are drawn to a vaccine against the cold-water disease in fish, comprising, as an effective component, inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

Kondo et al discloses a 36-hour culture that comprises *Flavobacterium psychrophilum*. Kondo et al discloses that this culture had the highest mortality of immersion infection, which indicates that the bacterium at the logarithmic culture phase has a high virulence (page 817, 1<sup>st</sup> column). The vaccine of the prior art is the same of that which is claimed. Claim limitations such as "vaccine" and "against the cold-water disease in fish " are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 458.

13. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by LaFrentz et al (Characterization of serum and mucosal antibody responses and relative per cent survival in rainbow trout, *Oncorhynchus mykiss* (Walbaum), following immunization and



challenge with *Flavobacterium psychrophilum*, Journal of Fish Diseases, 2002; 25: 703-13).

Claims 1-2 are drawn to a vaccine against the cold-water disease in fish, comprising, as an effective component, inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

LaFrentz et al discloses a vaccine that comprises killed *Flavobacterium psychrophilum* cells, which were effective against bacterial coldwater disease in fish (page 705 & 710; 1<sup>st</sup> column).

14. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by LaFrentz et al (Characterization of serum and mucosal antibody responses and relative per cent survival in rainbow trout, *Oncorhynchus mykiss* (Walbaum), following immunization and challenge with *Flavobacterium psychrophilum*, Journal of Fish Diseases, 2002; 25: 703-13).

Claim 3 is drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase or components of the cells.

LaFrentz et al discloses a method for preventing cold-water disease in rainbow trout by administering a vaccine that comprises killed *Flavobacterium psychrophilum* cells (pages 704- bacterial culture; 705-fish immunizations).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant

to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### **Conclusion**

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kondo et al (Adherence of *Flavobacterium psychrophilum* on the body surface of the ayu *plecoglossus altivelis*, Microbes and Infection, March 2002; 4: 279-83).

Kondo et al (Efficacy of oral vaccine against bacterial coldwater disease in ayu, Disease of Aquatic Organisms, 2003; 55(3): 261-64).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Handwritten signature, possibly "LRS", above the printed name.

**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**